

Appl. No. : 10/563,199
Filed : September 1, 2006

REMARKS

Applicant wishes to note that there are 56 claims pending in this application as they were filed in a Preliminary Amendment of January 3, 2006. Applicant attaches a copy of the filed document as downloaded from the PAIR.

Claims 1-7, 9, 18 and 19 have been amended to read on the elected organism.

Restriction to one of the following groups was required under 35 U.S.C. 121 and 372:

- Group I claims 1-15, 40-42, drawn to a vaccine composition for vaccinating dogs.
- Group II claims 16-19, drawn to a method of vaccinating, a method of treating, and a method of stimulating an immune response.
- Group III claims 29-30, drawn to a method of making an antibody.
- Group IV claims 32-34 and 55, drawn to a method of passively immunizing and method of treating.
- Group V claims 43, 44 and 50-51, drawn to a method of determining whether a dog has been exposed to a *Chlamydogophila* species.
- Group VI claims 45-51, drawn to a method of determining whether a dog has or susceptible.
- Group VII claims 52-53, drawn to an immunosorbent assay, a solid phase coated with anyone or more of an agent capable of raising an immune response.
- Group VIII claims 31, 38-39, drawn to an antibody and a composition.

In response to this Restriction Requirement, Applicant provisionally elects Group I, that is Claims 1-15 and 40-42, with traverse.

Organism election

Additionally, if Group I was elected, the Examiner has requested an election of a single organism or specific combination. In response to this restriction requirement, Applicant elects whole organism of *Mycoplasma cynos*.

The Restriction Requirement is improper because, according to PCT RULE 13.1: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention)". And, according to PCT RULE 13.2: "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or

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more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

In this case, the claims share the technical feature of the use of an agent capable of raising an immune response against *M. cynos* in a dog.

Novelty

In the International Search Report, the examiner identified a single document, EP 0415794 (D4), that mentions vaccines against *M. cynos*. However, the proposed claims are novel over EP 0415794 because: the vaccines of EP 0415794 comprise an antigen associated with the listed microorganisms. EP 0 415 794 does not disclose a whole organism vaccine against *M. cynos*.

Non-obviousness

The vaccine composition comprising *M. cynos* for vaccinating dogs is non-obvious for at least the following reasons.

As described in the introduction to the present application, canine infectious respiratory disease (CIRD) is a highly contagious disease common in dogs that are housed in re-homing centers and kennels. The severity of this disease can range from mild symptoms to bronchopneumonia and even death. As well as the suffering that CIRD causes to the dogs, it imposes a significant cost on owners of dog homes and kennels.

Although a number of infectious agents have previously been associated with CIRD, the available vaccines against CIRD based on these infectious agents are not particularly efficacious and do not provide a high level of protection against the disease. In the present application, the inventors have surprisingly and unexpectedly identified a significant correlation between the presence of *M. cynos* and the severity of CIRD in dogs. In example 2, the inventors have shown a significant increase in the percentage of dogs with *M. cynos* in the trachea or lung with respiratory disease. The inventors have also noted that the proportion of dogs with *M. cynos* infection in the kennel increases over time. Thus, whereas dogs entering the kennel have no detectable levels of *M. cynos*, by the second week 24% of the 184 dogs tested were *M. cynos* positive in the trachea. In other words, the inventors have demonstrated that there is both significant transmission of *M. cynos* between dogs in the kennels and a significant correlation of

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M. cynos with CIRD. These data strongly suggest that a vaccine composition against *M. cynos* would prevent the transmission of *M. cynos* between dogs in the kennels and hence reduce the level and severity of CIRD in these dogs.

Accordingly, it is only the work by the present inventors that provides any reason or motivation for the skilled person to prepare a vaccine composition comprising an agent that raises an immune response against *M. cynos* in a dog.

Therefore, the present claims are united by the same technical feature, and the restriction requirement is improper.

Rejoinder

The Examiner has required restriction between product and process claims. Applicant hereby elects claims directed to the product with the understanding that upon allowance of the product claims, withdrawn process claims of Group II that depend from or otherwise require all the limitations of the allowable product claim will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104.

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CONCLUSION


Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: September 4, 2007

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AMEND .

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